PHILIPS

K132068
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This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

The submitter of this pre-market notification is Philips Medical Systems
Theresa Poole
Regulatory Affairs Specialist
Patient Monitoring
Philips Medical Systems
3000 Minuteman Road, MS0480
Andover, MA 01810-1099

SEP 2 6 2013

Tel: 978 659 7621
Fax: 978 685 5624
Email: theresa.poole@philips.com

This summary was prepared on 1 July 2013

The name of this device is the Philips ECG algorithm Software Release PH100C. Classification names are as follows:

Classification	Pro Code	Description
Unclassified, Class II	74 LOS	ECG Analysis System
870.2340, II	74 DPS	Electrocardiograph

The new device is substantially equivalent to the previously cleared Philips ECG Algorithm software cleared under K020708 and K052049.

The Philips DXL 12/16-lead ECG Algorithm provides an analysis of the amplitudes, durations, electrical axis, and morphologies of the ECG waveforms and associated rhythms.

The new device has the same Indications for Use as the legally marketed predicate device.

Intended Use:
To analyze multi-channel ECG signals from adult and pediatric patients with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.

Indications for Use:
Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

The new device has the same technological characteristics as the legally marketed predicate device.

The modification also incorporates a subset of the diagnostic statement changes recommended in Wagner GS, Macfarlane P, Wellens H, Josephson M, Gorgels A, Mirvis DM, Pahlm O, Surawicz B, Kligfield P, Childers R, Gettes LS. AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram: part VI: acute ischemia/infarction: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Circulation. 2009;119:e262– e270.

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new algorithm with respect to the predicate. Testing involved use of standard ECG databases, system level tests, integration tests, and verification of risk mitigation identified in the hazard analysis. Results from interpretive ECG analysis programs are used as in an advisory nature. Physicians are required to over read each ECG report and also consider the ECG waveforms; the patient's clinical history before agreeing with the ECG analysis program statement. The Philips ECG Algorithm software meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 26, 2013

Philips Medical Systems
c/o Ms. Theresa Poole
Regulatory Specialist
3000 Minuteman Rd
Andover, MA 01810 US

Re: K132068
Trade/Device Name: Philips DXL 12/16-Lead ECG Algorithm
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, LOS
Dated: August 28, 2013
Received: August 29, 2013

Dear Ms. Theresa Poole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132068

2.0 Indications for Use

510(k) Number (if known): _____

Device Name: Philips DXL 12/16-lead ECG Algorithm

To analyze multi-channel ECG signals from adult and pediatric patients with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __N/A___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.26 16:09:27 -04'00'